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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/629,296 | 07/28/2003 | Yasunori Kawate | 11333/25 | 6488 |

7590 10/30/2008

Brinks Hofer Gilson & Lione
NBC Tower
Suite 3600
P.O. Box 10395
Chicago, IL 60610

| EXAMINER | |
|---|---|
| GABEL, GAILENE | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 10/30/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/629,296 | KAWATE, YASUNORI | |
| | Examiner | Art Unit | |
| | GAILENE R. GABEL | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *33-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 15, 2008 has been entered.

### *Withdrawn Rejections*

2. All rejections not reiterated herein, have been withdrawn.

3. In light of Applicant's amendment and arguments, the rejection of claims 33-41 under 35 U.S.C. 103(a) as being unpatentable over Oku et al. (US Patent 6,106,778) in view of Rodriguez et al. (US Patent 6,228,652), is hereby, withdrawn.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 33-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Rodriguez et al. (US Patent 6,228,652) in light of Nakashima et al. (US Patent 7,390,677).

Rodriguez et al. disclose an analyzer which comprises a sample preparing portion, a flow cell (interrogation zone), a light source, a first detector, and a second detector. The sample preparing portion is configured for subjecting samples to reagent. The light source is configured for irradiating the assay sample. The first detector detects and measures scattered light intensity and the second detector detects and measures fluorescence intensity of irradiated components present in the assay sample. Rodriguez et al. further teach that the analyzer includes an analyzing portion which analyzes fluorescence intensity measurements and scattered light intensities for performing counting and differentiation of blood cell types and detection of immunological reactions which result from binding between assay reagent/substance containing antibodies and antigen (cell surface antigen) present in the sample (Abstract; col. 4, line 28 to col. 5, line 18; and col. 5, lines 34-47). The sample preparing portion includes a reaction vessel, a reagent supply portion, and an assay sample supplier portion (Figure 1) so as to subject aliquots of samples, i.e. a first and a second aliquot, to different reagents such as fluorescent dye and monoclonal antibodies specific for the target substance (cell surface antigens) to be assayed present in the blood sample (col. 7, line 59 to col. 8, line 20 and col. 11, line 46 to col. 12, line 2). The light source may be any one of continuous wave laser, argon-ion laser, and diode-pumped solid state laser (col. 9, lines 26-34; col. 10, lines 44-56; and col. 13, lines 43-53). The different

light detectors are photodetectors which are configured to obtain optical information including scattered light intensity and fluorescence intensity from the sample which correspond to fluorescence spectra by different dyes and fluorochromes and binding interaction, i.e. agglutination, resulting from immunological binding interaction of the monoclonal antibodies with their corresponding target substance present in the sample (col. 8, lines 21-65 and col. 10, line 57 to col. 11, line 28). The analyzing portion counts and differentiates between erythrocytes (red cells), leucocytes (white cells), and platelets (col. 5, lines 18-28 and col. 7, line 58 to col. 8, line 20). The analyzing portion is configured to provide a measure of hematocrit value based on size information of blood cells (MCV and RBC). According to Rodriguez et al., the analyzing portion corrects immunoassay results, such as for hemoglobin, based on blood cell counting values (MCH and RBC) (col. 8, lines 49-60 and col. 14, lines 5-40).

In as far as the recitation of 1) use of a reagent (for introduction into the sample and binding interaction with target substance) comprising fluorescent carrier particles sensitized with antigen or antibody against a target substance in serum or plasma of the whole blood sample, and 2) measurement of irradiated fluorescent carrier particles in the assay sample by at least one of the detectors and determining agglutination degree of these fluorescent carrier particles, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Although Rodriguez et al. do not specifically teach use of fluorescent carrier particles sensitized with antigen or antibody against a target substance in serum or plasma of the whole blood sample as the basis of agglutination function measured to obtain concentration value of a specific target substance, which in this case is a soluble target substance present in serum or plasma of the whole blood sample, such a limitation is drawn to intended use of the structure and does not provide any further structural limitations to the apparatus which as recited, is inherently capable of doing. As an example, Nakashima et al. teach an immunoassay apparatus which comprises a sample preparing portion (sample supply section) having a reaction vessel (reaction plate) comprising a reagent supply portion (dispenser) for dispensing whole blood sample from a sample supplier and insoluble carrier particles sensitized with antigen or antibody directed against target substance present in the plasma portion of the whole blood sample, a flow cell, a light source (laser) for irradiating the particles passing through the flow cell with laser light, a detector (photo acceptance unit) for detecting scattered light generated on the basis of degree of agglutination of the reacted carrier particles, and an analyzing portion (data processing means) for setting threshold values on signals from the irradiated sample so as to distinguish between blood cells and agglutinated particles on the basis of scattered light intensity and for calculating and converting the degree of agglutination into the concentration of antigen or antibody present in the plasma portion of the whole blood sample (cols 5-9, especially col. 5, line 25 to col. 6, line 22). According to Nakashima et al., the detector and analyzing portion as taught by Rodriguez et al. which detect and measure scattered light intensity from

agglutinated carrier particles, are capable of detecting and measuring degree of agglutination from the measured scattered light intensity as a basis for determining the concentration of target substance that is present in the plasma portion of whole blood sample. Accordingly, the only distinction between Applicant's claims and the prior art is recited in the functional language. It is incumbent upon Applicant to show that the apparatus disclosed by the prior art is not actually capable of performing such functions. See In re Ludtke, 169 USPQ 563 @ 566 (CCPA 1971) and In re Swinehartetal, 169 USPQ 226 @ 229 (CCPA 1971).

***Response to Arguments***

5. Applicant's arguments with respect to claims 33-41 have been considered but are moot in view of the new grounds of rejection.

6. No claims are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

October 24, 2008